In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Case No. 13-521V

Filed: December 30, 2014

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DAVID ALEXANDER MAHER,	
	Special Master Nora Beth Dorsey
Petitioner,	
v.	Entitlement; Decision without a Hearing; Ruling on the Record;
SECRETARY OF HEALTH AND HUMAN SERVICES,	Tetanus Diphtheria Acellular Pertussis (Tdap) Vaccine; Neurologic Injuries.
Respondent.	
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Deborah Mandas Knopfler, Ventura, CA, for petitioner.
Claudia Barnes Gangi, U.S. Department of Justice, Washington, DC, for respondent.

DECISION ON ENTITLEMENT[1]

I. Introduction

On July 29, 2013, David Alexander Maher ("petitioner"), pro se, filed a petition for compensation under the National Vaccine Injury Compensation Program ("the Program" or the "Vaccine Act")[2], alleging that a tetanus, diphtheria and acellular pertussis ("Tdap") vaccination

[1] Because this unpublished decision contains a reasoned explanation for the action in this case, the undersigned intends to post this decision on the website of the United States Court of Federal Claims, in accordance with the E-Government Act of 2002 § 205, 44 U.S.C. § 3501 (2006). In accordance with the Vaccine Rules, each party has 14 days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Further, consistent with the rule requirement, a motion for redaction must include a proposed redacted ruling. If, upon review, the undersigned agrees that the identified material fits within the requirements of that provision, such material will be deleted from public access.

[2] The Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-10 et seq. Hereafter, individual section references will be to 42 U.S.C. § 300aa of the Act.

he received on July 28, 2010, caused him to sustain a "neurologic injury." Petition at 2. The medical records and information in the record, however, do not support a finding that petitioner is entitled to compensation under the Vaccine Act.

In this case, petitioner alleges both a "Table Injury" and a "causation-in-fact" injury. See § 300aa-13(a)(1). Here, the evidence does not support a finding of a Table Injury; thus a medical opinion as to causation is required. Petitioner has not offered such an opinion. See Petitioner's Motion for Ruling on the Record ("Pet'r's Motion") at 3. In lieu of filing a supportive expert opinion, petitioner requests that the Special Master "take Judicial Notice of the known and admitted side effects of the Tdap vaccine.… " Id. As explained below, even if the undersigned takes judicial notice as requested by petitioner, there is insufficient evidence to prove causation. For these reasons, and the reasons discussed below, petitioner has failed to demonstrate that he is entitled to compensation, and therefore, the petition is dismissed for insufficient proof.

II. Procedural History

Petitioner filed his petition pro se on July 29, 2013. No medical records were filed with the petition. On August 23, 2013, petitioner filed a motion requesting a 90 day enlargement of time to file his medical records, and requested that the initial status conference be delayed until the records were filed. Petitioner's request was granted. See Scheduling Order dated August 26, 2013. On November 20, 2013, petitioner filed exhibits A-H, a disability insurance certificate, and affidavits. The initial status conference was held on January 9, 2014. Mr. Maher appeared, as well as Ms. Debra Knopfler, an attorney that Mr. Maher had recently retained but who had not yet entered an appearance in the case. Ms. Claudia Gangi appeared on behalf of respondent. Pursuant to the discussions that took place during the conference, petitioner was ordered to file additional medical records requested by respondent. Id.

Ms. Knopfler was substituted as counsel of record for petitioner on February 28, 2014, and supplemental records were filed on March 10, 2014. A second status conference was held on April 24, 2014. Counsel for petitioner stated that she believed all outstanding records had been filed. Based on the discussions held during the status conference, respondent was ordered to file a status report by May 27, 2014, indicating whether she wished to pursue informal resolution of the claim or to propose a deadline to file the Rule 4(c) report. See Order filed April 25, 2014.

Respondent filed a status report on May 27, 2014, stating that respondent did not wish to pursue informal resolution and proposed a deadline of June 20, 2014, to file the Rule 4(c) Report. On June 20, 2014, respondent filed her report pursuant to Vaccine Rule 4(c), stating that the medical personnel of the Division of Vaccine Injury Compensation had reviewed the petition and medical records and concluded that the case was not appropriate for compensation under the Vaccine Act. See Respondent's Report ("Resp't's Rep't"), filed June 20, 2014, at 2.

Subsequently, a Rule 5 status conference was held on July 24, 2014. During that conference, the undersigned inquired whether the parties had discussed settlement or if the parties were interested in doing so prior to filing expert reports. Respondent's counsel stated that her client intended to defend the case unless petitioner could produce an expert opinion in

support of his claim. Petitioner was ordered to file an expert report by Monday, September 22, 2014. See Scheduling order filed July 24, 2014. Petitioner did not file an expert report. Instead, on October 21, 2014, petitioner filed a motion for a ruling on the record. Respondent did not file a response to the motion.

This case is now ripe for a decision on the record.

III. Summary of the Relevant Evidence[3]

a. The Petition and Petitioner's Affidavit

Petitioner was born on July 23, 1962, and was healthy and active prior to receiving the vaccination at issue. See Petition at 2; Ex. H at 1. Petitioner received a Tdap vaccination on July 28, 2010, at his place of work, Ventura County Medical Center, "following an exposure to a doctor that was later confirmed to have pertussis." Id. at 2. Approximately three hours later, petitioner stated that he began experiencing "high fever that lasted for 3 days, bedding that was saturated with sweat that had to be rewashed every few hours, and extreme fatigue and extreme sleepiness." Id.

Since July 28, 2010, petitioner alleged that his symptoms have become more frequent and severe. He stated that he has been "symptomatic for [e]ncephalitis, weak productive cough, severe weakness, severe sleepiness, trembling in extremities, severe headaches, seizure-like activity, confusion, fatigue, aphasia, poor balance, awkward movements, paralysis, personality changes, poor social skills, memory problems, disorientation, difficulty with activities of daily living, and employment problems." Petition at 2. Petitioner further alleged that he is no longer able to perform his former job of medical office assistant. Id.

On April 13, 2011, petitioner was sent home from work for having what a co-worker physician described as a tonic-clonic seizure. See Petition at 2. Petitioner was seen in the emergency department for uncontrollable shaking and body movements on May 10, 2011, May 11, 2011, and August 25, 2011. Id. Petitioner alleges that he sustained "a neurologic injury caused by the vaccine and that his ongoing condition is a sequelae of that disorder." Id.

b. Medical records

Prior to receiving the vaccination at issue, petitioner's medical history was significant for chronic lower back pain and degenerative disc disease. Ex. C2 at 133. He also had an "undiagnosed sleep disorder." Ex. H at 1.

From July 17, 2010 through July 25, 2010, petitioner was exposed to a co-worker who had a pertussis infection. Ex. I at 361 to 364. Due to that exposure, on July 28, 2010, petitioner received the Tdap vaccine and antibiotics from his employer. Pet. at 2; Ex. H at 1. On August 2, 2010, petitioner presented to Dr. Wilson Fung's office in Camarillo, California, for follow-up care related to his exposure to pertussis. Dr. Fung documented that petitioner had been on a Z-

[3] The undersigned has reviewed the entire record. See § 300aa-13(a)(1). This summary is not an attempt to present all relevant evidence, only a brief overview of some of the pertinent facts.

pack but was still symptomatic, with a productive cough, fatigue and decreased energy. Ex. I at 361. Dr. Fung took a medical history and documented petitioner's 30 plus year history of excessive daytime somnolence. Dr. Fung also noted that petitioner "falls asleep within minutes in quiet environment." Id. The nurse's note from that office visit confirms that petitioner's history of extreme daytime sleepiness had been a problem for 35 years. Id. Upon physical examination, petitioner had normal, unlabored respiratory effort and his lungs were clear to auscultation. Dr. Fung's diagnoses were: 1) occupational exposure to pertussis, and 2) sleep-related breathing disorder, narcolepsy/obstructive sleep apnea (OSA). Dr. Fung ordered antibiotics for the pertussis exposure and a sleep lab study for the diagnosis of narcolepsy/OSA. Id.

Dr. Fung referred petitioner to Dr. George C. Yu for a sleep consultation. Petitioner underwent a sleep study on September 2, 2010. Ex. C2 at 139. Subsequently, Dr. Yu saw petitioner on February 14, 2011, and documented petitioner's history as follows: "He has progressive daytime sleepiness for 30 years. He works night shifts. He had pertussis in 8/10. His sleepiness has worsened since. He has been on Adderall for depression and daytime sleepiness for about one year. He takes Adderall at different times about 6 days per week. He has worked night shift about 3/5 years…. He is still sleepy even with Adderall." Ex. C2 at 164. Dr. Yu concluded that petitioner's sleep study and work up were "suggestive but not diagnostic of narcolepsy without cataplexy" and "idiopathic hypersomnia." Id. Dr. Yu did not attribute petitioner's problems to the Tdap vaccination.

A number of other physicians also examined and evaluated petitioner. In July 2011, Dr. Allan D. Wu at UCLA performed an extensive work up on petitioner. Petitioner reported that he had developed a hand tremor the prior year, which had progressed to "shaking, posturing, and his jaw becoming more clenched intermittently… [g]radually, his head shaking started to appear." Ex. C4 at 195-96. Petitioner had involuntary movements with "constant bobbing of his head… and writhing movements of his arms." Id. at 197. Petitioner's neurological examination was normal. Id. Dr. Wu concluded that petitioner had a functional movement disorder[4] with "abnormal stereotyped movement patterns that are being expressed inappropriately" and recommended treatment with "coping strategies and re-adaptation." Id.

Petitioner saw Dr. Pari Young, a neurologist, who agreed with Dr. Wu that petitioner had a "functional movement disorder" with "possible late onset dystonia, psychomotor slowing and possible early cognitive deterioration." Ex. C1 at 84. In an office visit on August 17, 2012, Dr. Young noted that petitioner's abnormal movements had progressed to include "seizure-like episodes" with stiffening of the limbs. Ex. C1 at 98. An extensive work up was normal. Results from diagnostic studies including a CT scan, MRI, and EEG were all normal. Testing for genetic disorders, including Huntington disease and Wilson disease, did not show evidence of any abnormalities. Tests for rheumatologic disease were also normal. Id. Neurocognitive testing did not reveal any significant abnormality, other than some problem with short term memory. Petitioner questioned whether his symptoms were related to the Tdap vaccine. Dr. Young responded that while vaccine causation was possible, there was no evidence to support such a conclusion. Id. specifically, Dr. Young documented that while it was possible that petitioner

[4] A "functional disorder" is defined as a disorder of physiological function having "no known organic basis." Dorland's Illustrated Medical Dictionary, 550 (32d ed. 2012).

had "encephalitis and permanent brain damage from the vaccination… [his] MRI is negative for any evidence of demyelinating disease or other ischemia." Id. at 99.

Petitioner also saw Dr. Scott Tushla, a family practice physician, who diagnosed petitioner with "idiopathic hypersomnia" and a head tremor. Ex. C6 at 222. Dr. Timothy Sheehy, a neurologist, suspected that petitioner had a psychogenic movement disorder. Ex. C8 at 247-48. Dr. Lakshman Rasiah, a psychiatrist, concluded petitioner had an adjustment reaction disorder. Ex. C9 at 252-53. Erik Lande, Ph.D., a psychologist, determined that petitioner had normal cognitive function with some short term memory problems that were probably related to medication. Ex. C10 at 254. Finally, Dr. Stephen Rolanksy, an emergency room physician, suspected that petitioner had a neuropsychiatric disorder. Ex. C7 at 243. None of these physicians concluded that petitioner's condition was caused by the Tdap vaccine.

IV. Standard for Adjudication—Causation

The Vaccine Act established the Program to compensate vaccine-related injuries and deaths. § 300aa-10(a). "Congress designed the Vaccine Program to supplement the state law civil tort system as a simple, fair and expeditious means for compensating vaccine-related injured persons. The Program was established to award 'vaccine-injured persons quickly, easily, and with certainty and generosity.'" Rooks v. Sec'y of Health & Human Servs., 35 Fed. Cl. 1, 7 (1996) (quoting H.R. REP. No. 908 at 3, reprinted in 1986 U.S.C.C.A.N. at 6287, 6344).

To receive compensation under the Vaccine Act, petitioner must prove either: (1) that he suffered a "Table Injury"—i.e., an injury listed on the Vaccine Injury Table—corresponding to a vaccine that he received, or (2) that he suffered a "causation-in-fact" injury, that is an injury that was actually caused by the vaccine he received. See §§ 300aa-13(a)(1)(A) and 11(c)(1); Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1319-20 (Fed. Cir. 2006). Petitioner must show that a vaccine was "not only a but-for cause of the injury but also a substantial factor in bringing about the injury." Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1322 (Fed. Cir. 2010) (quoting Shyface, 165 F.3d at 1352-53 (Fed. Cir. 1994)).

To establish causation in fact, petitioner must show by a preponderance of the evidence that but for the vaccination, petitioner would not have been injured, and that the vaccination was a substantial factor in bringing about the injury. Cedillo v. Sec'y of Health & Human Servs., 617 F.3d 1328, 1338 (Fed. Cir. 2010); Shyface v. Sec'y of Health & Human Servs., 165 F.3d 1344, 1352 (Fed. Cir. 1999). Proof of actual causation must be supported by a sound and reliable "medical or scientific explanation that pertains specifically to the petitioner's case, although the explanation need only be 'legally probable, not medically or scientifically certain.'" Moberly, 592 F.3d at 1321 (quoting Knudsen v. Sec'y of Health & Human Servs., 35 F.3d 543, 548-49); see also Grant v. Sec'y of Health & Human Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992) (medical theory must support actual cause). "[A] petitioner must demonstrate the reliability of any scientific or other expert evidence put forth to carry this burden . . . . Expert testimony, in particular, must have some objective scientific basis in order to be credited by the Special Master." Jarvis v. Sec'y of Health & Human Servs., 99 Fed. Cl. 47, 54-55 (2011) (citing Moberly, 592 F.3d at 1322; Cedillo, 617 F.3d at 1339; Terran v. Sec'y of Health & Human Servs., 195 F.3d 1302, 1316 (Fed. Cir. 1999)).

"The special master…may not make [] a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." § 300aa-13(a)(1). Causation is determined on a case-by-case basis, with "no hard and fast per se scientific or medical rules." Knudsen, 35 F.3d at 548. A petitioner may use circumstantial evidence to prove the case, and "close calls" regarding causation must be resolved in favor of the petitioner. Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1280 (Fed. Cir. 2005).

If there is no Table Injury, petitioner must prove that the vaccine caused his injury. To do so, he must establish, by preponderant evidence: (1) a medical theory causally connecting the vaccine and the injury ("Althen Prong One"); (2) a logical sequence of cause and effect showing that a vaccine was the reason for his injury ("Althen Prong Two"); and (3) a showing of a proximate temporal relationship between the vaccine and injury ("Althen Prong Three"). Althen, 418 F.3d at 1278; § 300aa–13(a)(1) (requiring proof by a preponderance of the evidence).

a. There is no evidence of a Table Injury[5]

In his affidavit, petitioner states that the "Tdap vaccine…and resulting injury…is within the 'Vaccine Injury Table.'" Ex. H at 1. Petitioner alleges that approximately three hours after he received the vaccine on July 28, 2010, he had a high fever lasting for three days, and extreme fatigue and sleepiness. Petition at 2. Petitioner further alleges that from July 28, 2010 through the present date, he has had "[e]ncephalitis, weak productive cough, severe weakness, severe sleepiness, trembling in extremities, severe headaches, seizure-like activity, confusion, fatigue, aphasia, poor balance, awkward movements, paralysis, personality changes, poor social skills, memory problems, disorientation, difficulty with activities of daily living, and employment problems." Id.

Of the injuries alleged by petitioner, the only injury listed on the Table for the Tdap vaccine is encephalopathy (or encephalitis). 42 C.F.R. § 100.3 Vaccine Injury Table (2011). To be considered a Table Injury, the "first symptom or manifestation of onset or of significant aggravation" of encephalopathy must occur within 72 hours after administration of the vaccine. Id. The qualifications and aids to interpretation (QAI) that accompany the Table define encephalopathy for adults and children 18 months of age or older as an "acute encephalopathy… that persists for at least 24 hours and characterized by at least two of the following: (1) A significant change in mental status that is not medication related; specifically a confusional state, or a delirium, or a psychosis; (2) A significant decreased level of consciousness, which is independent of a seizure and cannot be attributed to the effects of medication; and (3) A seizure associated with loss of consciousness." 42 C.F.R. § 100.3(b)(2)(i)(B).

Here, petitioner does not allege any "significant change in mental status," "significant decreased level of consciousness" or "seizure associated with loss of consciousness" within 72 hours after receipt of the vaccine. While he alleges that he experienced fever, extreme fatigue and sleepiness, these signs and symptoms do not meet the definition of encephalopathy under the

[5] It is not clear whether petitioner intended to allege a Table Injury, but for the sake of completeness, the undersigned assumed that he did.

Vaccine Act. Moreover, the medical records do not support a finding that petitioner had an encephalopathy. In the first few days after receiving the vaccine, there is no evidence of a neurological injury. Petitioner had a cough, fatigue, decreased energy, fever, and sweats. But there is no medical record or other evidence which supports any finding that he had brain impairment.

There are several entries where physicians raise the issue of encephalitis, but petitioner was never diagnosed with that condition. Moreover, it appears that in these instances the question of encephalitis was raised by petitioner, and then rejected as a diagnosis by the physicians who treated petitioner. Dr. Rasiah documented a quote by petitioner that he was "suffering from the sequelae of an encephalitis" caused by the vaccine. However, this was not a diagnosis reached by Dr. Rasiah. Dr. Rasiah did not document or suggest in the records that petitioner had any sign or symptom of encephalopathy as defined by the QAI within 72 hours. See Pet. Ex. C9 at 251-52.

Similarly, Dr. Young documented petitioner's concerns about having encephalitis on August 17, 2012, more than one year after he received the vaccination. Dr. Young notes that petitioner "believes that all of his symptoms were the result of a Tdap vaccination." Dr. Young goes so far as to document that "[i]t is possible that [petitioner] had encephalitis," Pet. Ex. C1 at 99, but a mere possibility is not preponderant evidence. Even assuming that Dr. Young had made a diagnosis of encephalitis, there were no documented symptoms associated with encephalitis that occurred during the time frame required under the Vaccine Table.

For the above reasons, the undersigned finds that petitioner is not entitled to compensation based upon his allegation that he suffered a Table Injury.

b. The evidence does not prove causation under the Althen prongs

Petitioner has also failed to produce evidence or an expert opinion establishing that the vaccination caused his neurological injuries. In fact, petitioner "concedes the lack of a medical expert report causally linking his current disabilities to the vaccine." Pet'r's Motion for Ruling on the Record at 3. Petitioner instead requests that the undersigned take judicial notice of the known side effects of the Tdap vaccine, as published by the Centers for Disease Control, the Vaccine Injury Compensation Program website, and manufacturing labels. Id. Petitioner argues that the complications he suffered immediately after the vaccine are known side effects, and that expert opinion should not be required to establish causation "for the type of injuries suffered by petitioner, as identified in the records on file." Id.

Petitioner has seen a number of physicians, and he has been diagnosed with narcolepsy, OSA, idiopathic hypersomnia, functional movement disorder, psychogenic movement disorder, adjustment reaction, and neuropsychiatric disorder, among other things. These conditions are not the type of side effects or conditions for which the undersigned could take judicial notice as it relates to vaccine causation. An expert medical opinion is required to establish that any of these conditions are causally related to vaccination. Since petitioner has not submitted an expert report, there is no preponderant proof of causation. Petitioner has not proved Althen Prong One, as he has not provided any evidence of a medical theory showing how the vaccine can cause the

type of injuries he alleges. Petitioner has failed to prove Althen Prong Two, by not filing evidence that the vaccination caused his injuries consistent with a proposed medical theory. Petitioner has failed to prove Althen Prong Three, because there is no medical evidence or medical opinion that addresses the issue of an appropriate proximate temporal relationship between the vaccination and injury.

Therefore, petitioner has failed to provide preponderant evidence that his vaccination caused his alleged injuries.

V. Conclusion

For the reasons discussed above, the undersigned finds that petitioner has not established entitlement to compensation and his petition must be dismissed. **Therefore, this case is dismissed for insufficient proof. The Clerk shall enter judgment accordingly.**

IT IS SO ORDERED.

s/ Nora Beth Dorsey
Nora Beth Dorsey
Special Master